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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,651	08/30/2000	Michael Lassner	MTC 6718	1981

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/651,651	Applicant(s) LASSNER ET AL.	
	Examiner Russell Kallis	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,22,28,32,34,36,38,40-43,45-50,107,111,115,117 and 121-125 is/are rejected.
- 7) ☒ Claim(s) 113 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 10,22,28,32,34,36,38,40-43,45-50,107,111,113,115,117 and 121-125.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/19/2005 has been entered.

Claims 1-9, 11-21, 23-27, 29-31, 33, 35, 37, 39, 44, 51-106, 108-110, 112, 114, 116 and 118-120 are canceled. Claims are 10, 22, 28, 32, 34, 36, 38, 40-43, 45-50, 107, 111, 113, 115, 117 and 121-125 are pending and examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 43, 46-47 and 49-50 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must recite the multiple dependency in the alternative only. See MPEP § 608.01(n). Amending the claims to recite "said recombinant construct" would obviate this objection.

Claim Rejections - 35 USC § 112

Claims 10, 22, 28, 34, 36, 38, 40-43, 45-50, 107, 111, 115, 117 remain and new Claims 123-125 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/16/2004 and 6/16/2005. Applicant's arguments filed 3/21/2005 and 9/19/2005 have been considered but are not deemed persuasive.

Applicant asserts that the written description of the invention must clearly allow one of ordinary skill in the art to recognize the invention, and that it must be viewed from the perspective of one of skill in the art at the time of filing (response page 7). Applicant has claimed a genus of isolated polynucleotides yet has not defined that genus with respect to any specific structural features common to that genus and also fails to recite any specific function or activity associated with the claimed genus, and hence has not provided an adequate written description of the invention as broadly claimed.

Applicant asserts by further elaborating that techniques for amino acid substitution and the analysis thereof are well known in the art and discusses hydrophobicity and hydrophathy analysis with respect to protein modification (response pages 7 and 8). Applicant has not presented any coding sequences that have been modified or analyzed with respect to their hydrophobicity and hydrophathy as discussed.

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Applicants remarks directed to the Noiriél reference (Noiriél A. *et al.* European Journal of Biochemistry, 2004; Vol. 271, pages 3752-3764) on page 8 of the response clearly show that Applicant was not in clear possession of the invention as broadly claimed at the time of filing and thus Applicant's specification does not clearly allow one of ordinary skill in the art to recognize the invention as broadly claimed.

Moreover, when viewed from the perspective of one of skill in the art at the time of filing, Applicant was not aware of the specific activity of the enzyme encoded by SEQ ID NO: 4 (i.e. phospholipase A1 activity as described by Noiriél) and did not include this description in their specification or include an assay for its determination, and thus one of ordinary skill in the art would not recognize the invention as broadly claimed.

Applicant asserts that there is no basis in law to limit Applicants to any less than what is being claimed (response page 8). See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus."

Applicants fail to describe a representative number of isolated polynucleotides having at least 80% sequence identity to SEQ ID NO: 4; and isolated polynucleotides that hybridize to SEQ ID NO: 4. Further, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Moreover, Applicant has not described the specific activity or function of the claimed genus of polynucleotides, and thus has not described the genus as broadly claimed.

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Claims 10, 22, 28, 34, 36, 38, 40-43, 45-50, 107, 111, 115, 117 remain and new Claims 123-125 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant vector comprising an isolated polynucleotide of SEQ ID NO: 4 or an isolated polynucleotide encoding a polypeptide of SEQ ID NO: 5, and plants transformed therewith having increased total oil content in transformed seeds, does not reasonably provide enablement for any non-exemplified polynucleotides which are at least 80% complementary to SEQ ID NO: 4; or for non-exemplified polynucleotides that hybridize to SEQ ID NO: 4 under low stringency conditions; or plants transformed therewith in sense or antisense orientation that produce transformed seeds having an increase in sterol-esters, oil content or sterol content; or for plants transformed with LCAT2; i.e. SEQ ID NO: 4 producing transformed seeds having increased sterol-ester or increased phytosterol content or any non-specified alteration in oil production. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/16/2004 and 6/16/2005. Applicant's arguments filed 3/21/2005 and 9/19/2005 have been considered but are not deemed persuasive.

Applicant asserts that it is routine in the art to make changes to coding sequences and then assay for activity and states that The Detailed Description of the Invention describes those techniques that will retain or improve enzymatic activity (response page 9). Applicant has not set forth an enzymatic activity for LCAT 2; SEQ ID NO: 4 encoding SEQ ID NO: 5 or an assay that to distinguish it from what is known in the art. Moreover, Applicant has not provided working examples of enzymatic variants for any LCAT proteins taught in the specification, and thus

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undue trial and error experimentation would be required to make and use the invention as broadly claimed.

Applicant incorrectly asserts that the present claims relate to LCAT2 as possessing phospholipase activity (response page 12 lines 1-3) and further asserts that the working examples show activity for this sequence (response page 12 lines 3-4). There is no mention of phospholipase A activity in Applicant's specification or working examples; Applicant teaches only an increase in total oil content in seeds that comprise SEQ ID NO: 4, which does not define the specific activity of the encoded enzyme, the guidance for determining Applicant has not provided. Further, Applicant's elected invention drawn to SEQ ID NO: 4 does not produce phytosterols or esterified sterols when assayed *in vitro* and thus there is no *in vitro* characterization or assay of the polypeptide of SEQ ID NO: 5 encoded by SEQ ID NO: 4 that teaches how to predictably make and use the invention as broadly claimed. Further, Applicant's response that no conclusions can be made with respect to the LCAT2-like sequence does not fully acknowledge that the enablement art teaches that a likely candidate for lecithin:cholesterol acyltransferase (LCAT2; i.e. SEQ ID NO: 4) unexpectedly showed phospholipase A1 activity when transformed into Arabidopsis resulting in the accumulation of triacylglycerol (TAG) and fatty acids (FA) but no increases in sterol-esters (SE) demonstrating not only that LCAT2 is not an lecithin:cholesterol acyltransferase but also teaching that making assumptions about LCAT2-like sequences is unpredictable. (Noiriel A. *et al.* European Journal of Biochemistry, 2004; Vol. 271, pages 3752-3764; see Abstract lines 1-7; cloning of LCAT-like cDNAs on page 3753 in column 2; page 3757 column 2 beginning with line 4; and the Discussion beginning on page 3761 to page 3762 column 1 line 4; and bibliography reference 48a on page 3763).

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Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified polynucleotide sequences encoding non-exemplified LCAT2-like polypeptides (i.e. polynucleotides , by producing expression vectors to transform plants therewith and test for product formation, in order to identify those polynucleotides that when over-expressed or expressed in antisense orientation would produce plants that yield an increased oil content or some non-specified altered oil content in transformed seeds.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43, 46-47 and 49-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 recites the limitation "a polypeptide" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Amending the claim to recite "the polypeptide" would obviate this rejection.

Claim 49 recites the limitation "a plant" in line 1. There is insufficient antecedent basis for this limitation in the claim. Amending the claim to recite "the polypeptide" would obviate this rejection.

Claim Rejections - 35 USC § 102

Claims 10, 22, 28, 32, 34, 36, 38, and 40 remain and new Claims 121-125 are rejected under 35 U.S.C. 102(a) as being anticipated by Federspiel N. *et al.* Gene F21M11.5 as GenBank Accession Number AC003027 December 30, 1998 in light of The Institute for Genomic Research database annotation for Gene F21M11.5; see attachment. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/16/2004 and 6/16/2005. Applicant's arguments filed 3/21/2005 and 9/19/2005 have been considered but are not deemed persuasive.

Applicant asserts that the current claims are directed to coding sequences operably linked to a heterologous promoter functional in plants (response page 12). This is incorrect because the claims are drawn to an isolated nucleic acid sequence comprising a coding sequence wherein the isolated nucleic acid sequence not the coding sequence is operably linked to a heterologous regulatory sequence functional in plants. There is nothing in the claim stating that the coding sequence is operably linked to a heterologous promoter functional in plants. The isolated nucleic acid sequence only comprises the polynucleotide that encodes the polypeptide. The claims still read upon the BAC clone isolated by Federspiel *et al.* because the isolated nucleic acid sequence is the plasmid of the BAC clone and the 5' region of the gene encoding the LCAT protein comprises a promoter functional in plants that is heterologous to the plasmid. Amending the claims to recite "wherein the isolated polynucleotide encoding said polypeptide is operably linked to a heterologous regulatory sequence functional in plants", would obviate this rejection.

Applicant asserts that the Federspiel reference does not contain any annotation of the lecithin:cholesterol acyltransferase coding sequence and since the TIGR database reference

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contains no date for the entry of the annotation for locus F21M11.5 the activity of the protein encoded by the nucleic acid sequence would not have been known at the filing (response page 12) and that the specification states that an LCAT2 sequence could be identified within AC003027 (response page 13). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the nucleic acid sequence encodes a lecithin:cholesterol acyltransferase-like protein) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant asserts that the specification does not teach that the LCAT2 sequence and SEQ ID NO: 4 recited at page 31 in the specification are identical (response page 13). This is incorrect because the specification does indeed state that they are one and the same see line 28 of page 31, AC003027 referred to herein as LCAT2, SEQ ID NO: 4. Moreover, Applicant has not provided any evidence that the two sequences are not identical.

No claim is allowed.

Claims 41-43, 45-50, 107, 111, 113, 115, 117 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest plants or plant cells transformed with a recombinant construct comprising SEQ ID NO: 4 or host cells comprising SEQ ID NO: 4 that express SEQ ID NO: 5.

Claim 113 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the allowable limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
November 30, 2005

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

Russell Kallis